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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/750,143	12/31/2003	Maurice Behague	069208.0115	7930

23640 7590 02/19/2009

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EXAMINER	
HAND, MELANIE JO	

ART UNIT	PAPER NUMBER
3761	

NOTIFICATION DATE	DELIVERY MODE
02/19/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/750,143	BEHAGUE ET AL.	
	Examiner	Art Unit	
	MELANIE J. HAND	3761	

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 November 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) *6-17* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date. _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed November 17, 2008 have been fully considered but they are not persuasive. With respect to arguments regarding claim 1: Applicant argues that O'Riordan explicitly limits the disclosure to embodiments with pumps and therefore does not disclose allowing biological fluid to flow through the collection device of the collection bag without the use of a pump, O'Riordan discloses collection of biological fluid, blood, via a needle without the use of a pump. That fluid then flows directly to the collection bag having a fluid collection device, i.e. the needle. As stated in the previous action, no pump is present in the embodiment where the fluid is collected via a needle therefore O'Riordan discloses the step of allowing the biological fluid to flow through the fluid collection device to the collection bag **without the use** of a pump "as to the limitation "the fluid collection device of the fluid collection bag", there is no support for this limitation in the disclosure as originally filed. Specifically, Fig. 3 of applicant's disclosure clearly discloses a fluid collection device 3 that is physically separated from the bags 2 via first tube 6. Therefore the bag clearly does not have a fluid collection device.

2. With respect to arguments regarding claim 4: Applicant argues in addition to arguments based on those with respect to claim 1, that O'Riordan does not disclose or suggest the step of calculating the variation in weight of the fluid collected, this was acknowledged by the examiner, hence the rejection under 35 U.S.C. 103. The fact that the method of O'Riordan allows for a superfluous calculation for the variation in weight of fluid collected does not mean that adding that step to the method will be a disadvantage or that O'Riordan teaches away from adding such a step, as applicant appears to be arguing. As the step of performing this calculation is not explicitly taught by O'Riordan, examiner rejected the claim under 35 U.S.C. 103. The method of

O'Riordan clearly suggests such a step, a fact that applicant admits by stating that the calculation is "superfluous".

3. The double patenting rejection made in the Office action mailed May 7, 2007 is withdrawn in view of the amendment to the claims.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-5 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. With respect to claim 1, there is no support in the disclosure as originally filed for a fluid collection bag having a fluid collection device. The fluid collection device 3 as disclosed is clearly and repeatedly disclosed as being an entity that is physically separated from the bag by a tube. Thus the bag cannot have the device as claimed. Claims 2-5 are rejected because they depend from claim 1.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-3 and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by O'Riordan et al (EP 583,148 A2).

With respect to **claim 1:** O'Riordan teaches a method of collecting a biological fluid comprising collecting a biological fluid by natural flow via a needle (Page 3, lines 45-47) and without a pump, since the suction wand of the alternate embodiment of blood collecting means taught by O'Riordan is not used. The method further comprises the step of introducing a biological fluid collection bag 16 having a fluid collection device, i.e. the needle. With regard to limitations directed to the collection bag having a fluid collection device, in light of the rejection of claim 1 under 35 U.S.C. 112, the phrases "has a collection device" or "collection device of the collection bag" are given their broadest reasonable interpretation in light of the specification, i.e. "have" or "of" is interpreted as meaning "operatively connected to". The fluid collection device/needle is proximate to a biological fluid source, namely the arteriovenous system of a patient, and the needle is in fluid communication with the bag 16. (Fig. 4, Page 3, lines 24-27, 45-47, Page 4, lines 53-55) O'Riordan discloses the step of allowing the biological fluid to flow through the biological fluid collection device of the collection bag 16 to the bag without the use of a pump, inasmuch as the pumps disclosed by O'Riordan are the vacuum pump for the suction wand, which is not present in the embodiment having a needle in place of the wand, and the anticoagulant pump, which does not interact in any way with the fluid collection device. The

instant method also comprises the steps of measuring a fluid flow rate of the biological fluid via flow detector 22 (Page 5, lines 19-21), and pumping anticoagulant solution to the collected biological fluid at a solution flow rate. (Page 3, lines 51-55, page 4, lines 15-21, 47, 48) The solution flow rate is adjusted while collecting the biological fluid based upon the measured fluid flow rate to preserve a selected ratio between the collected biological fluid and the anticoagulant solution. (Page 3, lines 54, 55; Page 4, lines 15-48, Page 5, lines 19-23) Specifically, O'Riordan discloses in lines 47-48 that "with the above-described system, anticoagulant can be automatically delivered as a function of either volume of blood salvaged or the salvage rate" (i.e the volume of blood collected or blood collection fluid flow rate).

With respect to **claim 2:** The method taught by O'Riordan further comprises the step of pumping the anticoagulant and/or preservation solution to the collection bag 16 (Page 4, lines 53-55). The solution flow rate is adjusted while collecting the biological fluid based upon the measured fluid flow rate Qb to preserve a selected ratio in the collection bag 16 between the collected biological fluid and the anticoagulant and/or preservation solution. (Page 4, lines 15-33)

With respect to **claim 3:** The biological fluid taught by O'Riordan comprises blood. (Abstract)

With respect to **claim 5:** The method taught by O'Riordan comprises a step of pumping anticoagulant, wherein the act of pumping comprises pumping using a peristaltic pump 42 having a variable rotation speed, inasmuch as the minimum pump speed can be set and the operation of the pump is controlled to ensure maintenance of the desired flow rate of anticoagulant. (Page 3, lines 54, 55; Page 5, lines 4,5) The method also comprises adjusting the

variable rotation speed to obtain the appropriate solution flow rate. (Page 3, lines 54,55; Page 5, lines 4,5)

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over O'Riordan et al ('148).

With respect to **claim 4:** The method taught by O'Riordan comprises a step of measuring a fluid flow rate Qb, wherein measuring a fluid flow rate of the biological fluid comprises calculating the variation in volume of the fluid collected, wherein such volume has an associated weight directly correlated to said volume by the density of the biological fluid. O'Riordan does not teach that measuring a fluid flow rate of the biological fluid comprises calculating the variation in weight of the fluid collected. However, the data accumulated by performing the step of measuring the variation in volume can easily be used by one of ordinary skill in the art to calculate variation in weight by multiplying the variations in volume by the density of the fluid (know because the fluid is blood) and multiplying the resulting mass variation by the gravitational constant to produce the associated weight variations. Therefore, it would be obvious to one of ordinary skill in the art to modify the method taught by O'Riordan such that the step of measuring fluid flow rate Qb further comprises the step of calculating the variation in weight of fluid collected with a reasonable expectation of success to monitor the amount of fluid collected to determine when a

sufficient amount of blood has been collected and the process can be stopped.

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELANIE J. HAND whose telephone number is (571)272-6464. The examiner can normally be reached on Mon-Thurs 8:00-5:30, alternate Fridays 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Melanie J Hand/
Examiner, Art Unit 3761

/Tatyana Zalukaeva/

Supervisory Patent Examiner, Art Unit 3761